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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0729; FRL-10603-01-OCSPP]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on mango, papaya, and oil palm. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0729, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-2875; email

address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0729 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are

provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0729, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of May 20, 2022 (87 FR 30856) (FRL-9410-13), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F8946) by Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.507 be amended by establishing an import tolerance for residues of the fungicide azoxystrobin, methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate, in or on palm, oil at 0.06 parts per million (ppm). The petition also requested to amend tolerances in 40 CFR 180.507 for residues of the fungicide azoxystrobin in or on mango at 4 ppm and papaya at 6 ppm. The May

20, 2022, notice of filing referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *https://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for azoxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with azoxystrobin follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety

determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for azoxystrobin, most recently on November 15, 2018, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to azoxystrobin and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from the 2018 rulemaking as described further in this rulemaking, as they remain unchanged.

A. Toxicological Profile

For a discussion of the toxicological profile of azoxystrobin, see Unit III.A. of the 2018 rulemaking (83 FR 57333) (FRL-9985-45).

B. Toxicological Points of Departure/Levels of Concern

For a summary of the toxicological points of departure/levels of concern used for the safety assessment, see Unit III.B. of the 2018 rulemaking.

C. Exposure Assessment

Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. The updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the 2018 rulemaking.

Dietary exposure from food and feed uses. EPA's dietary exposure assessments have been updated to include the increased exposure from the amended tolerances of azoxystrobin on mango and papaya and the additional exposure associated with the import tolerance on palm oil. For the acute dietary exposure assessment, EPA used tolerance-level residues for all commodities, except citrus fruits (which used the highest residues from residue trials), 100 percent crop treated (PCT) for all commodities, and default processing factors with the Dietary Exposure Evaluation Model (DEEM) for all commodities except where tolerances were established for processed commodities. For the chronic dietary exposure assessment, EPA used

tolerance-level residues for all commodities, 100 PCT for all commodities, and default processing factors with DEEM for all commodities except where tolerances were established for processed commodities.

Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for azoxystrobin. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

Drinking water, non-occupational, and cumulative exposures. Drinking water exposures and residential (non-occupational) exposures are not impacted by the amended uses and import tolerance in this action. Since the last rulemaking in 2018, Registration Review was completed for azoxystrobin, resulting in updated estimated drinking water concentrations (EDWCs). The dietary risk assessment for this petition used the updated surface water EDWCs of 69.4 ppb for acute exposure and 20.7 ppb for chronic exposure, which were calculated with the Surface Water Concentration Calculator (SWCC).

Azoxystrobin is currently registered for use on turf, ornamentals, and antimicrobial uses as a materials preservative in paints and plastics that could result in residential exposures. The residential risk estimate that was used in the aggregate assessment is hand-to-mouth incidental oral exposures to preserved vinyl flooring for children aged 1 to less than 2 years old.

EPA's conclusions concerning cumulative risk remain unchanged from the 2018 rulemaking.

D. Safety Factor for Infants and Children

EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor to 1X for all exposure scenarios except acute exposure. For assessing acute dietary risk, EPA continues to retain an FQPA factor of 3X. See Unit III.D. of the 2018 rulemaking for a discussion of the Agency's rationale for that determination.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 29% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 66% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

The Agency analyzed short-term aggregate risk by aggregating chronic dietary (food and drinking water) exposure with incidental oral hand-to-mouth post-application exposure to children 1 to <2 years old from preserved vinyl flooring. EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 200 for children 1 to <2 years old. Because EPA's level of concern for azoxystrobin is an MOE of less than 100; this MOE is not of concern.

As stated in Unit III. E. of the 2018 rulemaking, azoxystrobin is not expected to pose an intermediate-term risk; therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate.

Based on the lack of evidence of carcinogenicity in two acceptable rodent carcinogenicity studies, azoxystrobin is not expected to pose a cancer risk to humans.

Therefore, based on these risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to azoxystrobin residues. More detailed information can be found at *https://www.regulations.gov* in the document titled "Azoxystrobin.

Human Health Risk Assessment for the Establishment of Tolerances for Residues in/on Mango and Papaya and Establishment of a Tolerance for Residues in/on Imported Palm Oil." in docket ID number EPA-HQ-OPP-2021-0729.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the 2018 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex

The Codex has established MRLs for azoxystrobin in or on mango at 0.7 ppm and papaya at 0.3 ppm, which are lower than the current U.S. tolerances for residues of azoxystrobin in or on mango at 2.0 ppm and papaya at 2.0 ppm. The petitioner requested increasing the tolerance for mango to 4 ppm and the tolerance for papaya to 6 ppm to support the import of these commodities from other countries. The residue data support the increased tolerances. Codex has not established an MRL for residues of azoxystrobin in or on palm oil.

V. Conclusion

Therefore, an import tolerance is established for residues of azoxystrobin, methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate, in or on palm, oil at 0.06

ppm, and existing tolerances are amended for azoxystrobin residues in or on mango at 4 ppm and papaya at 6 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus,

the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 14, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.507, in paragraph (a)(1) amend the table by:

a. Adding a heading for the table;

b. Revising the entry for "Mango";

c. Adding in alphabetical order the entry "Palm, oil";

d. Revising the entry for "Papaya"; and

e. Adding footnote 2 at the end of the table.

The additions and revisions read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * * * *	
Mango	4
* * * * * * *	
Palm, oil[2]	0.06
Papaya	6
* * * * * * *	

* * * * *

[2] There are no U.S. registrations on palm, oil as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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[FR Doc. 2023-05597 Filed: 3/17/2023 8:45 am; Publication Date: 3/20/2023]